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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,423	07/08/1999	JOACHIM B. KOHN	P-22577-H-US	8089

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EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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09/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/350,423	Applicant(s) KOHN ET AL.	
	Examiner Nihir Patel	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05.16.2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-38 is/are pending in the application.
- 4a) Of the above claim(s) 15-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>3</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on May 15th, 2006 have been fully considered but they are not persuasive. The applicant argues that Kohn does not disclose diphenol monomers with pendant carboxylic acid groups. The examiner disagrees column 5 lines 1-10 and lines 60-67 clearly disclose diphenol monomers with pendant carboxylic acid group.
2. In response to applicant's arguments, the recitation "a hydrolytically unstable diphenol polymer" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).
3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "with a pendant free carboxylic acid group may be prepared") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
4. The applicant also argues that Kohn does not disclose copolymers of diphenol monomers with pendant benzyl carboxylate groups and diphenol monomers with carboxylate pendant esters that are not benzyl esters or other ester group that are removed by hydrogenation. The examiner

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disagrees column 4 line 5-55 clearly disclose copolymers of diphenol monomers with pendant benzyl carboxylate groups and diphenol monomers with carboxylate pendant esters that are not benzyl esters or other ester group that are removed by hydrogenation.

5. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "block copolymers of polyarylates and poly(alkylene oxides) in which the polyarylate is prepared from two diphenol monomers, one with pendant benzyl carboxylate groups and one with carboxylate pendant esters that are not benzyl esters or other esters groups that are removed by hydrogenation") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims **1-4 and 6-8** are rejected under 35 U.S.C. 102(b) as being anticipated by Kohn et al. (US 5,670,602).

8. As to **claim 1**, Kohn discloses a synthesis of amino acid-derived bioerodible polymers that comprises that describes the structure illustrated in the claim wherein R9 is an alkyl, aryl or alkylaryl group with up to 18 carbon atoms having a pendent carboxylic acid group or the benzyl ester thereof (see **column 5 lines 1-5 and column 5 lines 60-65**); wherein R12 is an alkyl, aryl,

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alkylaryl group with up to 18 carbon atoms having a pendent carboxylic acid ester group selected from the group selected from the group consisting of straight and branched alkyl and alkylaryl esters containing up to 18 carbon atoms and ester derivatives of biologically and pharmaceutically active compounds covalently bonded to the polymer, provided that the ester group is not a benzyl group that is removed by hydrogenolysis (**see column 4 lines 5-15**).

9. **As to claim 2**, Kohn discloses an apparatus wherein R₉ has a structure selected from the group consisting of the structure described in the claim, wherein R₂ is hydrogen or a benzyl group and a and b are independently 0, 1 or 2 (**see column 5 lines 60-67**).

10. **As to claim 3**, Kohn discloses an apparatus wherein R₉ has the structure described in the claim, wherein a is 2 and b is 1 (**see column 3 lines 40-45**).

11. **As to claim 4**, Kohn discloses an apparatus wherein the pendent group of R₉ is a benzyl carboxylate group (**see column 4 lines 5-15**).

12. **As to claim 6**, Kohn discloses an apparatus wherein R₁₂ has a structure selected from the group consisting of the structure described in the claim, wherein R₁ is selected from the group consisting of straight and branched alkyl and alkylaryl groups containing up to 18 carbon atoms and derivatives of biologically and pharmaceutically active compounds covalently bonded to the polymer; and c and d are independently 0, 1 or 2 (**see column 5 lines 60-67**).

13. **As to claim 7**, Kohn discloses an apparatus wherein R₁₂ has the structure described in the claim, wherein c is 2 and d is 1 (**see column 3 lines 40-45**).

14. **As to claim 8**, Kohn discloses an apparatus wherein the ester group of the pendent carboxylic acid ester group of R₁₂ is a straight-chained alkyl group selected from the group consisting of ethyl, butyl, hexyl and octyl groups (**see column 4 lines 5-15**).

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15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims **1 and 9 through 14** are rejected under 35 U.S.C. 102(e) as being anticipated by Kohn (WO 97/19996).

17. **As to claim 1**, Kohn discloses a synthesis of amino acid-derived bioerodible polymers that comprises that describes the structure illustrated in the claim wherein R₉ is an alkyl, aryl or alkylaryl group with up to 18 carbon atoms having a pendent carboxylic acid group or the benzyl ester thereof (**see page 7 lines 5 and 6**); wherein R₁₂ is an alkyl, aryl, alkylaryl group with up to 18 carbon atoms having a pendent carboxylic acid ester group selected from the group selected from the group consisting of straight and branched alkyl and alkylaryl esters containing up to 18 carbon atoms and ester derivatives of biologically and pharmaceutically active compounds covalently bonded to the polymer, provided that the ester group is not a benzyl group that is removed by hydrogenolysis (**see page 7**).

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18 **As to claim 9**, Kohn discloses an apparatus that comprises a block copolymerized with poly(alkylene oxide) repeating units, each poly(alkylene oxide) repeating unit comprising between about 5 and 3000 alkylene groups containing up to 4 carbon atoms (**see page 7 lines 10-15**).

19. **As to claim 10**, Kohn discloses an apparatus wherein the alkylene group of each alkylene oxide is ethylene (**see page 9 lines 15-16**).

20. **As to claim 11**, Kohn discloses an apparatus that comprises each poly(alkylene oxide) repeating unit contains between about 20 and about 200 alkylene oxide groups (**see page 9 lines 15-18**).

21. **As to claim 12**, Kohn discloses an apparatus that comprises block copolymerized with poly(alkylene oxide) repeating units, each poly(alkylene oxide) repeating unit comprising between about 5 and about 3,000 alkylene oxide groups containing up to 4 carbon atoms (**see page 9 lines 15-18**).

22. **As to claim 13**, Kohn discloses an apparatus wherein the alkylene of each alkylene oxide is ethylene (**see page 9 lines 10-20**).

23. **As to claim 14**, Kohn discloses an apparatus that comprises each poly(alkylene oxide) repeating unit contains between about 20 and about 200 alkylene oxide groups (**see page 9 lines 15-18**).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

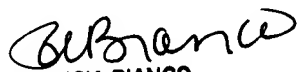
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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9/3/07